DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 24, 2014

Interventional Spine, Incorporated
Ms. Jane Metcalf
Vice President Quality Assurance, Regulatory and Clinical Affairs
13700 Alton Parkway, Suite 160
Irvine, California 92618

Re: K140716
Trade/Device Name: Opticage™ Expandable Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 20, 2014
Received: October 23, 2014

Dear Ms. Metcalf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140716

Device Name
Opticage™ Expandable Interbody Fusion Device

Indications for Use *(Describe)*
The Opticage™ Expandable Interbody Fusion Device is a lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Interbody Fusion Device can be implanted via posterior, transforaminal or lateral approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had a six month course of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

APPLICANT:	Interventional Spine, Inc.
DATE PREPARED:	November 24, 2014
CONTACT PERSON:	Jane Metcalf 13700 Alton Parkway, STE 160 Irvine, CA 92618 Phone: 949.525.1493 Fax: 949.472.0016
TRADE NAME:	Opticage™ Expandable Interbody Fusion Device,
COMMON NAME:	Spinal Implant
CLASSIFICATION NAME:	Intervertebral Body Fusion Device
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	888.3080 (product code: MAX)
PRIMARY PREDICATE:	• Caliber® Spacer (K123231)
SECONDARY PREDICATES:	• L-Varlock Lumbar Cages (K080537) • Caliber™ Spacer (K102293)
REFERENCE DEVICES:	• Opticage Interbody Fusion Device (K113527) • Opticage™ Interbody Fusion Device, Model, Sterile (K132479) • Opticage™ Expandable Interbody Fusion Device, Model Series 9070 (K133583)

Purpose of Submission

There are two purposes for this 510(k) submission. The first is to modify the Indication for Use Statement to include the word "lateral". The second is to achieve market clearance for additional larger sizes of the Opticage Expandable Interbody Device, Model Series 9070.

Substantially Equivalent To

The Opticage Expandable Interbody Fusion Device, Model Series 9070 is substantially equivalent in intended use, principal of operation and technological characteristics to the primary predicate, Caliber® Spacer (K123231).

510(k) Summary

Device Description

The Opticage Expandable Interbody Fusion Devices, Model Series 9070 are designed for lumbar intervertebral body fusion via posterior, transforaminal or lateral approach. The devices are fabricated from titanium alloy (Ti-6AI-4V) as per ASTM Fl36. Each device consists of an upper and lower titanium plate, two titanium wedges and a central shaft. The two titanium wedges are connected by the central shaft. The shaft can be rotated to move the wedges toward the center of the device thereby increasing the distance (i.e. height) between the upper and lower titanium plates. Alternatively, the shaft can be rotated in the opposite direction to move the wedges away from the center of the device causing the distance (i.e. height) between the upper and lower plates to decrease. In this manner, the height of the construct can be continuously adjusted. The devices are available in a several footprint sizes. The top and bottom of the devices are fenestrated and each contain windows to enhance bony in growth. A cavity internal to each device is intended to hold autogenous bone graft.

The Opticage Expandable Interbody Fusion Devices in Model Series 9070 are provided in both sterile and non-sterile versions.

Indication for Use

The Opticage™ Expandable Interbody Fusion Device is a lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Expandable Interbody Fusion Device can be implanted via posterior, transforaminal, or lateral approach.

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510(k) Summary

Technical Characteristics

The Opticage Expandable Interbody Fusion Devices in Model Series 9070 have similar size, shape and material composition as the predicates, although the Caliber predicates (K102293 and K12332) also contain PEEK material that is not contained in the Opticage devices. Operational characteristics of all of the predicates are similar to the Opticage in than they can be expanded in situ via a special tool designed to interface with the expansion mechanism of the device. Graft material may be added to the internal cavity of all of the devices and all of the devices have windows in the top/bottom to allow the graft material to interface with the upper and lower vertebral endplates. Fenestrations are used on the top and bottom of all the devices to provide stability in the intervertebral space.

Performance Data

All necessary performance testing, has been completed for the Opticage Expandable Interbody Fusion Device, Model Series 9070 including loading paradigms identified in ASTM F2077-03 (static and dynamic compression, static and dynamic compression shear, static and dynamic torsional), subsidence per ASTM F2267, expulsion, and evaluation of wear debris/particulates per ISO 17853 and ASTM F1877. Finite element analysis (FEA) has been conducted to confirm worst case performance configuration.

Test performance data demonstrated substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence

Upon reviewing the performance data provided in this submission and comparing intended use, design, materials, principle of operation and overall technological characteristics, the Opticage Expandable Interbody Fusion Device, Model Series 9070 is determined by Interventional Spine, to be substantially equivalent to existing legally marketed devices.